Billing Code 4410-09-M

DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION IMPORTER OF CONTROLLED SUBSTANCES NOTICE OF REGISTRATION CAPRICORN PHARMA, INC.,

By Notice dated March 8, 2012, and published in the Federal Register on March 20, 2012, 77 FR 16262, Capricorn Pharma, Inc., 6900 English Muffin Way, Unit A, Frederick, Maryland 21703, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Fentanyl (9801), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically manufactured FDF. This analysis is required to allow the company to export domestically manufactured FDF to foreign markets.

In reference to the import of Fentanyl (9801), the authorization for the import of this basic class of controlled substance is granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 USC § 823(a) and § 952(a) and determined that the registration of Capricorn Pharma, Inc., to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Capricorn Pharma, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 USC § 952(a) and § 958(a), and in accordance with 21 CFR § 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: May 15, 2012

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